

**SYSTEM AUDIT REPORT NUMBER** 04/35812/TV02/AS-S03



**THIS REPORT RELATES TO A/AN SURVEILLANCE/TRIENNIAL VISIT ON 6/22-25/04**

**Company:** Marshal Space Flight Center

**Other Sites Visited:**

1. N/A

**Address:** Marshall Space Flight Center, A L 35812

2. N/A

**Scope:**

ISO 9001:2000: All Products and Services Provided by the Marshall Space Flight Center. MSFC Supports the NASA Agency Infrastructure and is a Major Contributor to All Its Scientific and Technical Enterprises.

AS9100: Design, Development, Production, Installation and Servicing of Flight Hardware, Flight Software, and associated Ground Support Equipment Interfacing with Flight Hardware and Fight Software.

**Standard(s):** AS 9100B

**Support Documentation(s):** AS9101B

**Non-English Languages Used:** N/A

**Comments/Concerns of the Assessment Team:**

Noncompliances noted are minor in nature

Previously identified noncompliance has been rewritten in this report.

Recommend continued registration to AS 9100

**The visit is deemed to be:**

- ☒ Satisfactory  
☐ Unsatisfactory

*Unsatisfactory visits may result in a change to the next audit activity.*

**Corrective Action Plan (CAP) Instructions:**

- ☒ Return CAP in 20 working days (all NCs, Obs & OIs). Certificate processing initiates after receipt/acceptance of CAPs.  
☐ AS & QS-9000 NCs must be closed prior to certificate issuance.  
☐ Return CAP in ten days for Major NCs issued during surveillance.

**NQA ASSESSMENT TEAM**

**LEAD AUDITOR:** Rick Giguere

**TEAM:** Trudy Keaveney

**TEAM:**

**TEAM:**

**TEAM:**

**COMPANY INFORMATION**

**MGT. REP.:** Axel Roth

**QUALITY MANUAL (REV & ISSUE DATE):**

Rev. M May 26, 2004

The contents of this report is confidential and must not be disclosed to a third party without the prior agreement of NQA, USA and the company named above. Non-compliances/non-conformances raised or observations noted within this report are the result of limited sampling and therefore non-compliances/non-conformances may exist which have not been identified. The Internal Audit system is deemed effective unless noted within the body of this report. The company representative's signature indicates their agreement and understanding of any non-compliances/non-conformances and observations contained in this report. Prior to the assessment, the company must have completed a complete system internal audit and subsequent management review documented. The quality system shall be understood throughout the organization.

**NQA, USA Representative Signature and Date:**

**Company Representative Signature and Date:**

Page 1 of 4

## AUDIT MATRIX

X or √ indicates reference point for assessment. X or √ through entire box as applicable to indicate actual function/process audited against the ISO 9001:2000 requirement. X or √ in next visit block indicates planned section for next activity. Estimated duration is 45 minutes.  Note: Asterisk (*) indicates requirement to be reviewed at each activity.		SPECIFIC ISO 9001:2000 REQUIREMENTS FUNCTIONS/PROCESSES AUDITED DURING THIS VISIT														NEXT VISIT PLAN
		Management Rep	QD 50, MTM	QD02, PMC	QD 40	HEI	TD 73/ QD 12/ AD10	MPLM / FD24/ COLSA	MSG / SD4/SD44/SD43	QD 30/ ED 37	PRL ad20/20	ECLSS /ED24/20	QD30/QD40/PS30	AD50	ED 43	
ISO 9001:2000 Reference	Clause Title															
4.2.1 & 4.2.2*	Quality Manual *					X										X
4.2.3	Document Control							X	X	X					X	
4.2.4	Quality Records							X	X	X					X	X
4.1, 5.1, 5.2, 5.3, 5.4.2, 5.5	Management Activities	X														
5.4.1*	Quality Objectives*	X	X	X												X
5.6*	Management Review *	X	X	X												X
6.1 & 6.2	Resources & Competence							X	X	X						
6.3 & 6.4	Infrastructure & Work Environment							X	X	X						
7.1	Product Realization Planning							X	X	X						X
7.2	Customer Related Process & Comm.										X	X				X
7.3	Design & Development										X	X				
7.4	Purchasing												X			
7.5.1 & 7.5.3	Process Provision and ID&T Activities							X	X	X						
7.5.2	Process Validation								X							
7.5.4	Customer Property							X	X	X	X			X		
7.5.5	Preservation (Handling, Storage & Deliv.)								X	X						
7.6	Calibration								X	X						
8.1	Measurement & Monitoring Planning						X									X
8.2.1*	Customer Satisfaction*	X														X
8.2.2*	Internal Audits*				X											X
8.2.3	Measurement &Monitoring of Process						X									
8.2.4	Measurement & Monitoring of Product						X									
8.3	Non-Conforming Processes/Products						X	X	X	X						
8.4	Analysis of Data	X	X	X												X
8.5.1*	Continuous Improvement*	X		X												X
8.5.2 & 8.5.3*	Corrective/Preventive Action*		X	X	X		X									X
Use of NQA Logo		X														X
Note: Please fill in the table including areas/sites/departments/functions visited during the visit.																
Page 2 of 41																

Note: Please fill in the table including areas/sites/departments/functions visited during the visit.

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**SYSTEM AUDIT REPORT NUMBER** 04/35812/TV02/AS-S03



**SYSTEM AUDIT RECORD**

**Auditor(s):** Rick Giguere Trudy Keaveney

**Date:** June 22-25, 2004

Clause No.	Record of Details of Audit (names, referenced documents, depts., etc.)	NC	Obs or OIs
4/5	See AS 9101 B checklist INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:	3	
6	See AS 9101 B checklist INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:		
7	See AS 9101 B checklist INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:	3	1
8	See AS 9101 B checklist INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:	2	

<b>TOTAL</b>	8	1
<b>PAGE 3 OF 4</b>		

Ref No.	Clause No.	NON-CONFORMANCES & OBSERVATIONS/OPPORTUNITIES FOR IMPROVEMENT RAISED	NC/OBS/OI
1	4.2.3	Test Discrepancy Reports are not completed in a consistent manner.	NC
2	7.4	Qualification criteria, thresholds of performance and consequences of poor performance have not been identified.	NC
3	7.4	Required actions when issued during supplier audits that introduce a potential risk are not identified. Ref: Sierra Lobo NDE Audit item#11, General finding polyolefin and nylon in space flight application, omission of mettalographic inspection in work instructions.	NC
4	8.5.2	Supplier corrective actions do not demonstrate full root cause corrective action anlysis. ref: Sierra Lobo audit finding corrective actions.	NC
5	7.4	Supplier has performed work for the organization since 10/02; audit of supplier for qualification is just being completed. Ref: Sierra Lobo.	NC
6	8.2.2	Reference NQA audit 03/35812/AS-S02, noncompliance item 1. Corrective action for this noncompliance could not be satisfactorily verified at this time. A review of internal audit records reveals that objective evidence is lacking of audits extending to AS 9100 requirements as specified in MPG 1280.6.	NC
7	5.6	MPG 7120.4 Appendix I: PPA Monthly Health Status Report requires that root cause of any yellow or red condition and recovery plan be described. A review of these reports reveals inconsistencies in the reporting of cause analysis and recovery plans in roughly half of the projects/programs reporting.	NC
8	4.3	MPG 8040.1, Configuration Management, MSFC Programs/Projects, Par. 3.4.2 states that Each program and/or project office shall ensure that periodic CM system audits of in-house CM activities be conducted. A review of CM audits reveals that it is CM itself that initiates these audits, and not the program or project office. Certain programs, such as Solar B and Dart, have declined audits.	NC
		(Continued from above)It is not likely that CM audits would be conducted without the initiative of the CM group.	
9	7.5.1	In Bldg. 4619, certain pressure gages were noted with operational check labels on them that had expired due dates. Although these are not calibration labels, there could be some confusion as to their validity with stickers indicating that operational checks are overdue.	OBS

NQA USA Representative Signature and Date:  6/25/04	Company Representative Signature and Date:  for Axel Roth 6/25/04	Page 4 of 4
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## AEROSPACE STANDARD

**SAE AS9101**  
Technically equivalent to  
AECMA prEN 9101

REV.  
B

Issued 2000-09  
Revised 2003-03

Superseding AS9101A

### Quality Management Systems Assessment

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<http://www.sae.org>

**SAE WEB ADDRESS:**

## **SAE AS9101 Revision B**

### **FOREWORD**

In December 1998, the Aerospace Industry has established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream.

This organization, with representation from Aerospace companies in Americas, Asia and Europe and sponsored by SAE, SJAC and AECMA has agreed to take responsibility for the technical contents of this standard.

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QUALITY MANAGEMENT SYSTEMS - ASSESSMENT

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## SECTION 1

\* \* \*

## QUALITY MANAGEMENT SYSTEMS ASSESSMENT




## 1 PURPOSE

The purpose of this document is to define the content and the presentation of the Assessment Report of the section 1 of AS9100.

## 2 QUALITY SYSTEM ASSESSMENT REPORT CONTENT

The Assessment Report is made up of:

- Page 6 (*required*)  
**General Assessment Information**
- Page 7 (*required*)  
**Assessment Conclusions**
- Page 8 (*optional*)  
**General Organization Information**
- Page 9 (*required*)  
**Assessment Result Summary**
- Page 10 (*required*)  
**Assessment Scoring**
- Page 11  
**Corrective Action Request (when required)**
- Page 12  
**List of Recommendations/Observations/Comments**
- **Appendix A**  
**Quality System Questionnaire relative to the section 1 of AS9100**

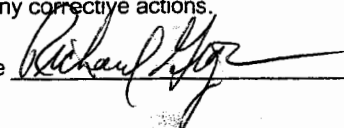
ASSESSMENT REPORT			Assessing company logo
<b>GENERAL ASSESSMENT INFORMATION</b>			
<b>1 Organization &amp; Work Address</b>			
Company Name: <u>NASA - MSFC</u>  Subsidiary of: Organization Identification: Assessed Site Address: <u>MARSHALL SPACE FLIGHT CENTER, AL</u> <u>35812</u>  Main activities: Product Types or Codes:	Tel Number: <u>(256) 544- 8361</u> Fax Number: <u>(256) 544- 4155</u> e-mail: <u>don.miller@msfc.nasa.gov</u> CAGE code: <u>21, 33, 34</u> Assessment Representative & Title: <u>Axel Roth - Mgmt Rep</u> Quality Manager Representative & Title: <u>Axel Roth - Mgmt Rep</u>		
<b>2 ISO Registration</b>			
<input checked="" type="checkbox"/> ISO Registered <input checked="" type="checkbox"/> ISO Standard / Revision <u>9001: 2000</u> <input checked="" type="checkbox"/> Aerospace Standard / Revision <u>AS 9100</u>	Registrar Name: <u>NQA-USA</u> Expiration Date (If applicable):		
<b>3 Assessment Team</b>			
Lead Assessor Name: <u>A03158</u> <input checked="" type="checkbox"/> Certified Auditor – Type & No. <u>Q03158</u> <input type="checkbox"/> Qualified Auditor	Other Assessor Team Members: <u>TRUDY KEAVENEY</u>		
<b>4 Assessment Dates:</b> <u>JUNE 22-25, 2004</u>			
<b>5 Assessment Scope</b>			
<input checked="" type="checkbox"/> Total facility assessed <input type="checkbox"/> Initial assessment <input type="checkbox"/> Partial facility assessed <input type="checkbox"/> Re-assessment <input type="checkbox"/> Other: <input type="checkbox"/> Activity assessed:	<input checked="" type="checkbox"/> All 9100 elements assessed <input type="checkbox"/> Partial 9100 elements assessed Elements not assessed:		
<b>6 Assessment Disposition</b>		<b>7 Scoring</b>	
<input type="checkbox"/> Conforming <input checked="" type="checkbox"/> Conforming with minor (mi) corrective action <input type="checkbox"/> Non conforming with Major (MA) corrective action		Scoring result: <u>91</u>	
<b>8 Assessment Approval</b>			
Assessing Company	Date	Lead Assessor Name	Signature
<u>NQA-USA</u>	<u>June 25, 2004</u>	<u>Rick Giguere</u>	<u></u>

**Distribution Agreement**

This Assessment Report is the property of the assessed Organization and the assessing Company. Distribution to other companies or individuals is authorized only after written agreement of the assessed Organization and of the assessing Company.

To that end, a signature below by an Authorized Representative of the assessing company indicates that this report may be copied by the organization for other customers.

If copied, the report must be disclosed in full including findings and any corrective actions.

Authorized Representative Rick Giguere Signature  Date 6/25/04

**ASSESSMENT REPORT**Assessing company  
logo**ASSESSMENT CONCLUSIONS****General comments about the organization and the quality system of the assessed organization:***See audit report***Strong points:**

- *Environmental Engineering Dept - 2004 Implementation Plan provides clear indication of objectives flow down from NASA.*

**Improvement Opportunities:**

**ASSESSMENT REPORT***Assessing company  
logo***GENERAL ORGANIZATION INFORMATION****1 Legal and Financial Aspects**☐ Date of Formation:☐ Legal Status:☐ Capital:☐ Other Data:

	Third Prior Financial Year ( )	Second Prior Financial Year ( )	First Prior Financial Year ( )	Current Financial Year ( )
<b>Sales</b>				
<b>Earnings</b>				
<b>Earnings used for Re- Investment</b>				
<b>Workforce</b>				

**2 Turnover breakdown and main Customers**

Activities	Main Customers	Sales Percentage
<b>Aircraft, Space and Defense Industry</b>		
<b>Other Activity (be specific)</b>		

**3 Clearances or Approvals granted by Authorities**

Name of the Authority	Types and References	End of Validity (date)

## ASSESSMENT REPORT

Assessing company  
logo

## ASSESSMENT RESULT SUMMARY

Organization : NASA

Elements* (AS9100 – Section 1)	Result				Observation / Corrective Action Request Number (MA/mi)
	S	Ma	mi	N/A	

## 4 - Quality Management System

4.1 General requirements

4.2 Documentation requirements

4.3 Configuration Management

## 5 - Management responsibility

5.1 Management commitment

5.2 Customer focus

5.3 Quality policy

5.4 Planning

5.5 Responsibility, authority and communication

5.6 Management review

## 6 - Resource management

6.1 Provision of resources

6.2 Human resources

6.3 Infrastructure

6.4 Work environment

## 7 - Product realization

7.1 Planning of product realization

7.2 Customer-related processes

7.3 Design and development

7.4 Purchasing

7.5 Production and service provision

7.6 Control of monitoring and measuring devices

## 8 - Measurement, analysis and improvement

8.1 General

8.2 Monitoring and measurement

8.3 Control of nonconforming product

8.4 Analysis of data

8.5 Improvement

Assessed Organization: NASA

Rep's name: Axel Roth

Signature: *[Signature]* for Axel Roth

Results

Assessing Company: DQA-USA

Lead Assessor Name: Rick Giguere  
Signature:

\* For each element, cross results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor or "N/A" for non applicable

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ASSESSMENT SCORING						(Member logo)	
Organization :		Result					
SCORING CHART		Major CAR or minor CAR on Key requirement		Minor CAR on non Key requirement		NO CAR	RESULT
		Multiple findings	Single finding	Multiple findings	Single finding		
4	Quality management system					(100)	
4.1	General requirements	0	10	25	40	50	50
4.2 & 4.3	Documentation requirements & Configuration management	0	10	25	40	50	25
5	Management responsibility					(150)	
5.1	Management commitment						
5.2	Customer focus	0	5	15	20	30	30
5.3	Quality policy						
5.4	Planning	0	10	20	30	40	40
5.5	Responsibility, authority and communication	0	5	15	20	30	30
5.6	Management review	0	10	25	40	50	40
6	Resource Management					(100)	
6.1	Provision of resources	0	10	25	40	50	50
6.2	Human resources						
6.3	Infrastructure	0	10	25	40	50	50
6.4	Work environment						
7	Product realization					(450)	
7.1	Planning of product realization	0	5	15	20	30	30
7.2	Customer related processes	0	10	30	50	60	60
7.3	Design and development						
7.3.1	D & D Planning	0	5	15	20	30	30
7.3.2-3.4	Inputs, outputs & review	0	5	15	20	30	30
7.3.5-6	D&D verification & validation	0	5	15	20	30	30
7.3.7	Control of design and development changes	0	5	15	20	30	30
7.4	Purchasing	0	10	30	50	60	30
7.5	Product and service provision						
7.5.1	Control of production and service provision	0	10	25	40	50	50
7.5.2	Validation of processes for production and service provision	0	10	20	30	40	40
7.5.3	Identification and traceability	0	10	20	30	40	40
7.5.4-5	Customer property & preservation of product	0	5	15	20	30	30
7.6	Control of monitoring and measuring device	0	5	10	15	20	20
8	Measurement analysis and improvement					(200)	
8.1	General	0	5	10	15	20	20
8.2	Monitoring and measurement						
8.2.1	Customer satisfaction	0	5	10	15	20	20
8.2.2	Internal audit	0	5	15	20	30	20
8.2.3	Monitoring and measurement of processes	0	5	15	20	30	30
8.2.4	Monitoring and measurement of product	0	5	15	20	30	30
8.3	Control of nonconforming product	0	5	15	20	30	30
8.4	Analysis of Data	0	5	10	15	20	20
8.5	Improvement	0	5	10	15	20	15
TOTAL						880 <sup>(1)</sup> or 1000	910
SCORE						910	100 91

The assessed Organization agrees on the Quality System scoring and Corrective Action requests

Organization Representative :

Don Miller for Axel Roth

Signature :

Don Miller for Axel Roth

Date :

6/25/04

(1) When 7.3 is not assessed : SCORE = RESULT X 100

880

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<b>CORRECTIVE ACTION REQUEST (C.A.R.)</b>			<i>Assessing company logo</i>
Organization:		Identification C.A.R. No.:	
Site:		Date issued:	
Reference Standard:		Referenced Standard Element concerned:	
Criticality Ma / mi	Non-Conformance Description		
Assessor Name:		Assessor Signature:	
Assessed Organization to complete the Corrective Action Request with root cause analysis, corrective action and planned completion date of corrective action, and return to the assessing Company by due date.			Due date:
Action No.:	Root Cause:		
Action No.:	Corrective Action:		Planned completion date of Corrective Action:
Organization Representative Name:		Signature:	Current date:
<b>Verification of the implementation of the completed Corrective Action by the Assessed Organization</b>			
Organization Representative Name:		Signature:	Current date:
<b>Verification of the implementation of the completed Corrective Action to be filled out by the Assessing Company</b>			
<u>Verification date :</u>	Accepted: Yes <input type="checkbox"/> No <input type="checkbox"/>	<u>Assessor Name :</u>	<u>Assessor Signature :</u>

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## List of Recommendations/Observations/Comments

Assessing company  
logo

Organization :

NASA

Audit report number

04/35812/IV02/AS-503

Site :

Huntsville

Issued date :

6/25/04

Item Number

Section

Description

See Nonconformance  
Report.

Lead Assessor Name:

Signature:

Rick Giguere



S : Satisfactory - CAR : Corrective action required - Ma : Major corrective action - mi : Minor corrective action  
N/A : Not applicable - N/E : Not evaluated - P : Product - M : Management



**APPENDIX A  
AS9101**

**\* \* \***

**QUALITY SYSTEM QUESTIONNAIRE**

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### 1. PURPOSE

The purpose of this document is to present the questionnaire to be used during the "on site" quality system assessment of Organizations in order to ensure common practices for these assessments. This questionnaire is relative to the section 1 of AS9100.

### 2. USE OF THE QUESTIONNAIRE

The use of this questionnaire is mandatory and will be a part of the Assessment Report. The questionnaire is used to evaluate AS9100 standard, section 1.

The audit is undertaken by review against the requirements of the questionnaire and the findings are recorded as appropriate by annotation of respective columns,

- Satisfactory (S)
- Not applicable (N/A) the reason shall be documented in the bottom of the page
- Not evaluated (N/E)
- Corrective Action Request (CAR) Major (Ma) or Minor (mi.) finding:

The CAR number shall be referenced in the column "CAR number"  
The category Ma for Major CAR or mi for Minor CAR shall be included in this column also.

#### Additional information on questionnaire

**Key Requirements:** Some requirements are deemed to be very significant and are so identified by the presence of 'P' or 'M' against the specific section or question within the questionnaire,

"P" direct link with product

"M" direct link with Management

The extent of Key Requirement applicability is determined by the location of the 'M' or 'P'. In the example below all of question 14 is considered as a key requirement.

<b>14</b> Does the output from the management review include any decisions and actions related to : a) Improvement of the effectiveness of the quality management system and its processes ? b) Improvement of product related to customer requirements ? and c) Resource needs ?	M					
--	---	--	--	--	--	--

In the second example below only part of question 03, i.e. d) is considered Key Requirement.

<b>03</b> In planning product realization, does the organization determine the following, as appropriate : a) Quality objectives and requirements for the product ? b) The need to establish processes, documents, and provide resources specific to the product ? c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance ? d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ? e) <i>The identification of resources to support operation and maintenance of the product ?</i>	P					
---	---	--	--	--	--	--

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**Guidance notes:** Certain questions will have a numeric reference that refers to additional guidance notes which are detailed within the 'Guidance notes' section located after the questions on each page. The guidance notes provide the Auditor with further insight on type of objective evidence and/or review expectations etc. In the example below, note (1) refers the auditor to additional notes pertaining to question 1 part a).

48 Does the analysis of data provide information relating to :					
a) Customer satisfaction (see 8.2.1) (1) ?					
b) Conformity to product requirements (see 7.2.1) e ?					
c) Characteristics and trends of processes and products including opportunities for preventive action ? And					
d) Organizations ?					

### Guidance Note

- 1) Give examples and check how the organization measures the effectiveness.

**References :** When a reference (e.g. 4.1) is added to a question, It is linked to the appropriate chapter (e.g. 4.1) of AS9100.

### Objective evidence assessed / Observations / Comments / N/A explanation

Record the objective evidence reviewed during the assessment or reason for not applicable.

### Non-conformities :

**Major :** The absence of, or total breakdown of a management element specified in the 9100 standard or any non-conformities where the effect is judged to be detrimental to the integrity of the product or service.

**Minor :** A single system failure or lapse in conformance with a procedure relating to the 9100 standard.

**Note :** A number of minor non-conformities against one requirement can represent a total breakdown of the system and this can be considered as a major non-conformity

## 3. USE OF THE ASSESSMENT SCORING CHART

Following completion of each chapter of the Quality System Questionnaire the nomenclature Assessment Scoring chart can now be completed.

The findings of each section and sub-section of the completed Quality System Questionnaire are reviewed and the Assessment Scoring sheet completed as follows.

- If, multiple findings (i.e. greater than 1) with Major (Ma) Corrective Action Request (CAR) or minor (mi) CAR on Key requirement in a section, e.g. 4.1 General Requirements then score in Major CAR or minor CAR on Key Requirement (i.e. any questions with 'M' or 'P' indicator) "Multiple findings" column (result = 0), or
- If, single finding with Major (Ma) CAR or minor (mi) CAR on key requirements in a section, e.g. 4.1 General Requirements then score in Major CAR or minor CAR on Key Requirement "Single finding" column (result =10), or
- If, multiple findings on non Key requirement (i.e. greater than 1) with Minor (mi) (CAR) in a section, e.g. 4.1 General Requirements then score in Minor CAR on non Key requirement "Multiple findings" column (result=25), or

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- If, single finding on non Key requirement with Minor (mi) CAR in a section, e.g. 4.1 General Requirements then score in Minor CAR on non Key requirement "Single findings" column (result = 40), or
- If, no CAR in a section, e.g. 4.1 General Requirements then score in "NO CAR" column (result=50)
- When a single finding occurred on several questions affecting the same section of the scoring table (e.g. 4.2 & 4.3 or 5.1-5.2-5.3), then score as "multiple findings".

### Further notes on scoring

The above review criteria should be considered sequentially.

Maximum audit total can be,

1000, where audit review comprises whole Quality System Questionnaire or,

880, where audit review comprises Quality System Questionnaire less Design and Development. In this case, the final score =  $\frac{\text{TOTAL} \times 100}{880}$

If a complete section line of the score sheet has not been assessed (N/A or N/E) the score will be calculated as follow:

$$\text{Score} = \frac{\text{TOTAL} \times 100}{\text{Sum of maximum possible score}}$$

The higher the score the greater the level of compliance acknowledged by the audit activity.

**Summary**

<b>Section headings</b>		<b>Page numbers</b>
<b>4</b>	<b>QUALITY MANAGEMENT SYSTEM</b>	<b>18</b>
<b>4.1</b>	<b>General requirements</b>	<b>18</b>
<b>4.2</b>	<b>Documentation requirements</b>	<b>19 – 20</b>
<b>5</b>	<b>MANAGEMENT RESPONSIBILITY</b>	<b>21</b>
<b>5.1</b>	<b>Management commitment</b>	<b>21</b>
<b>5.2</b>	<b>Customer focus</b>	<b>21</b>
<b>5.3</b>	<b>Quality policy</b>	<b>21</b>
<b>5.4</b>	<b>Planning</b>	<b>21</b>
<b>5.5</b>	<b>Responsibility, authority and communication</b>	<b>22</b>
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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 4 QUALITY MANAGEMENT SYSTEM

## 4.1 General requirements

01 Has the organization established, documented, implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard ?			✓			
02 Does the organization : a) identify the processes needed for the quality management system and their application throughout the organization (1) ? b) determine the sequence and interaction of these processes (1) ? c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective ? d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes ? e) monitor, measure and analyze these processes ? and f) implement actions necessary to achieve planned results and continual improvement of these processes ?			✓			
03 Are these processes managed by the organization in accordance with the requirements of this International Standard ?			✓			
04 Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes ?	P		✓			
05 Is the control of such outsource processes identified within the quality management system ?			✓			

Note : Processes needed for the quality management system referred to above should include processes for management, provision, product realization and measurement.

## Guidance Note

1) Main process formally identified e.g. : list, flow diagram, etc.

## Objective evidence assessed / Observations / Comments / N/A explanation

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 4.2 Documentation requirements

## 4.2.1 General

- 06 Does the quality management system documentation include :
- a) documented statements of a quality policy and quality objectives ?
  - b) a quality manual ?
  - c) documented procedures required by this International Standard ?
  - d) documents needed by the organization to ensure the effective planning, operation and control of its processes ?
  - e) records required by this International Standard (see 4.2.4) ? and
  - f) *quality system requirements imposed by the applicable Regulatory Authorities ?*

✓

- 07 Does the organization ensure that personnel have access to quality management system documentation and are aware of relevant procedures ?

✓

- 08 Do Customer and/or regulatory authority representatives have access to quality management system documentation ?

✓

## 4.2.2 Quality manual

MPD 1280.1 Rev M

- 09 Has the organization established and maintained a quality manual that includes (1) :
- a) the scope of the quality management system, including details of, and justification for, any exclusions ?
  - b) the documented procedures established for the quality management system, or reference to them, and *when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2) ?*
  - c) a description of the interaction between the processes of the quality management system ?

✓

**Note 1 :** Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

**Note 2 :** The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel

## Guidance Notes

- 1) Quality manual reference and issue
- 2) Check the procedure list

## Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed Mgmt Review meeting minutes  
 Reviewed change to Manual over triennial period  
 Sampled access to documents at various segment of audit.  
 procedures - on-line.

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
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SAE AS9101 Revision B

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

4.2 Documentation requirements (continued)

4.2.3 Control of documents

10 Are the documents required by the quality management system controlled ?

M

✓

11 Are records controlled according to the requirements given in 4.2.4 ?

✓

12 Has a documented procedure been established to define the controls needed to :

- a) approve documents for adequacy prior to issue ?
- b) review and update as necessary and re-approve documents ?
- c) ensure that changes and the current revision status of documents are identified ?
- d) ensure that relevant versions of applicable documents are available at points of use ?
- e) ensure that documents remain legible and readily identifiable ?
- f) ensure that documents of external origin are identified and their distribution controlled ? and
- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose ?

✓

13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements ?

✓

4.2.4 Control of records

14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system ?

✓

15 Do records remain legible, readily identifiable and retrievable (1) ?

✓

16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records ?

✓

17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers ?

✓

18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements ?

✓

4.3 Configuration management MWI 8040.2 RVC

19 Has the organization established, documented and maintained a configuration management process appropriate to the product ?

P

#8  
KC

Guidance Note

- 1) List records reviewed

Objective evidence assessed / Observations / Comments / N/A explanation

SSCN 8479, 3578

CCB Code - Effectivity Sheet

CPTAS Approved Master Report per MWI 8040.2

data entered into CPTAS. - MP 00065

Form 2327 March 98

Form 2896 May 02

Form 3418 Nov 01

Solar B - no config Mgmt office - neither contractors per 8040.1  
Dart - " " " " RVC per 3.4-2

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

CM Audit dated, 12/8/03 of (OSP) X-3720-



Config Audits - MSSR-1	7/03	Audit Rpt (03- )
X-37	11/03	(03- )
WGLT-REP	12/03	(04-001)
(PTIP) . 2/04		(04-005)
ISS NOOE	4/04	(04-010)

X-37 Project - Request to perform audit (memo) 10/23/03  
 Report of Audit results 12/8/03

4.3 Lisa Cooper Node 2/3 Project Office CM Plan SSNPs NC-0015  
 Level III CCB RWA  
 Membership of CCB - Charter letter - approved by project sign

Ch Request ISS - SSN 004652 → change evaluation →

PIRN - Berlin Interface Rev. Notice - PIRN 50314-NA-0005A  
 IFM # WDO2-0017 - Approves PIRN

Directive ⇒ OK IRN 50314-11, 12 Approved  
 4 of 6 CCB members Sign w/ proj. Mgr. concurrence  
 chairperson

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 4.2 Documentation requirements (continued)

4.2.3 Control of documents *TD 70-002 By Directorate*

10 Are the documents required by the quality management system controlled?

M

S

11 Are records controlled according to the requirements given in 4.2.4?

*yes TDR summary not complete*

S

*mi*

12 Has a documented procedure been established to define the controls needed to:

- a) approve documents for adequacy prior to issue? *yes*
- b) review and update as necessary and re-approve documents? *yes doc control repo*
- c) ensure that changes and the current revision status of documents are identified? *yes*
- d) ensure that relevant versions of applicable documents are available at points of use? *electronic files*
- e) ensure that documents remain legible and readily identifiable? *yes*
- f) ensure that documents of external origin are identified and their distribution controlled? and *yes*
- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? *yes*

S

13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements?

*as required*

S

## 4.2.4 Control of records

14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?

*yes*

S

15 Do records remain legible, readily identifiable and retrievable (1)?

S

16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?

*yes*

S

17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers?

*yes*

S

18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements?

*yes*

S

## 4.3 Configuration management

19 Has the organization established, documented and maintained a configuration management process appropriate to the product?

P

✓

## Guidance Note

1) List records reviewed *Contracts, Purchase Orders, Test, COFR, TDR, DR, Material Review Board*

Objective evidence assessed / Observations / Comments / N/A explanation

*Electronic Procedures & work instructions, grad on-line System Reviewed on-line System verified release and revisions*

\* 4.2.3 TDR not consistently filled out correctly SPICE 001

4.2.4 by SD 40-OWI-003 by MFSC Plan 305-2, Integration Review Panel Reports, minutes, Integration Review Action Chlosures Records custodian

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 5 MANAGEMENT RESPONSIBILITY

## 5.1 Management commitment

01 Has Top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by (1):

M

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements ?
- b) establishing the quality policy ?
- c) ensuring that quality objectives are established ?
- d) conducting management reviews ? And
- e) ensuring the availability of resources ?

5.1/5.2/5.3  
5 top mgmt interviews  
conducted during last  
audit

## 5.2 Customer focus

02 Has Top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1) ?

## 5.3 Quality policy

03 Has Top management ensured that the quality policy :

- a) is appropriate to the purpose of the organization ?
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system ?
- c) provides a framework for establishing and reviewing quality objectives ?
- d) is communicated and understood within the organization (2) ? and
- e) is reviewed for continuing suitability ?

## 5.4 Planning

## 5.4.1 Quality objectives

04 Has Top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organization (3) ?

05 Are the quality objectives measurable and consistent with the quality policy ?

M

## 5.4.2 Quality management system planning

06 Has Top management ensured that :

- a) the planning of the quality management system is carried out in order to meet the requirements (see 4.1), as well as the quality objectives ? and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented ?

## Guidance Notes

- 1) Evidence of management commitment
- 2) Identify and records method of communication
- 3) Review objectives and status of their implementation

## Objective evidence assessed / Observations / Comments / N/A explanation

examined policy and internal review of policy for adequacy  
Reviewed objective and performance against the same as evidenced in  
Balanced Scorecard

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 5.5 Responsibility, authority and communication

## 5.5.1 Responsibility and authority

07 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization (1) ?

✓

## 5.5.2 Management representative

08 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes :

M

- a) ensuring that processes needed for the quality management system are established, implemented and maintained ?
- b) reporting to top management on the performance of the quality management system and any need for improvement ?
- c) ensuring the promotion of awareness of customer requirements throughout the organization ? and
- d) the organizational freedom to resolve matters pertaining to quality ?

✓

## 5.5.3 Internal communication

09 Has Top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system ?

✓

## Guidance Note

1) Identify and records method of communication within the organization

## Objective evidence assessed / Observations / Comments / N/A explanation

*evaluated responsibilities + authorities - particularly as it related to  
CCB membership, MPB membership,  
approval of documents*

- *Interviewed Axel Roth, Mgmt Rep. as part of 5.6.*
- *Observed Internal Communication at various point of audit*

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N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

HPG - 7120.4

5.6 HSC/PMC - Program Management Council  
8.4 project/program evaluation . (Red, yellow, green)  
8.5.3 Stop light charts by project + psm  
- Green, yellow, red -

7120.4 for I.1.1 . require Cause + c/m for reds/yellows - Not done on  
Considered basis  
yellow/red require explanation of problem  
and action plan.

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
------------------	---	------------------------	-----	-----

## 5.6 Management review

## 5.6.1 General

10 Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness (1) ?

✓

11 Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives ?

/

12 Are records from management reviews maintained (see 4.2.4) ?

/

## 5.6.2 Review input

13 Does the input to management review include information on (2) :

M

- a) results of audits?
- b) customer feedback?
- c) process performance and product conformity?
- d) status of preventive and corrective actions?
- e) follow-up actions from previous management reviews?
- f) changes that could affect the quality management system? And
- g) recommendations for improvement?

/

## 5.6.3 Review output

14 Does the output from the management review include any decisions and actions related to (2) :

M

- d) improvement of the effectiveness of the quality management system and its processes?
- e) improvement of product related to customer requirements? And
- f) resource needs?

/

N/A

## Guidance Notes

- 1) Records management review frequency and functions involved (e.g : quality, production, etc.)
- 2) Verify the availability of input / output data such as: statistical data; graphics; summary tables; reports; etc.

## Objective evidence assessed / Observations / Comments / N/A explanation

5/25/04 - Mgmt Review - Axel Roth

Success Stories -

- MOC actions - Tracking action item
- Customer feedback reporting -
- Objectives - Continued Learning
- Safety
- MOC - Process Perf - Prod. Conf.
- Int Audit
- CIA/PA Program - RCAR
- Changes that could effect
- Objectives

Dennis Davis -  
Safety, MTR, QDSD

8.4

5/26 Report for FY 04

8.5.3

- Lost Time Rate
- OSHA Recordable
- all Cases
- unsafe Acts

Corrective action - Status

Safety data -

RCAR mgmt council

See adjacent page

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

Chris Smith - Truck Driver - CDL Class B

	<u>Forklift</u>			
Don Welton -	cert exp. 4/06	cl. 1, 5	Active	
David Green -	exp 4/05	Class 1-7	Active	
Rich Fletcher -	exp 7/04	cl 1, 5	Active	
Ben Franklin -	✓ 7/04	"	"	

John Harris - Recg Forklift 7/04 Active

Cedric Corn Recg " 1/07 Active

Aerospace Engineer position description # 32578 - Jim Lindsay

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 6. RESOURCE MANAGEMENT

## 6.1 Provision of resources

- 01 Has the organization determined and provided the resources needed:
- a) to implement and maintain the quality management system and continually improve its effectiveness ? And
  - b) to enhance customer satisfaction by meeting customer requirements ?

✓

## 6.2 Human resources

## 6.2.1 General

- 02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1) ?

✓

## 6.2.2 Competence, awareness and training

- 03 Does the organization :
- a) determine the necessary competence for personnel performing work affecting product quality (2) ?
  - b) provide training or take other actions to satisfy these needs ?
  - c) Evaluate the effectiveness of the actions taken ?
  - d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives ?
  - e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3) ?

P

✓

## 6.3 Infrastructure

- 04 Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements ?
- Infrastructure includes, as applicable :
- a) buildings, workspace and associated utilities ?
  - b) process equipment (both hardware and software) ? And
  - c) supporting services (such as transport or communication) ?

✓

## 6.4 Work environment

- 05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements ?

P

✓

**Note :** Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

## Guidance Notes

- 1) Review training Records and Plan (status of the current year and of the previous year)
- 2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill, ...)
- 3) Review training certificates for the certified personnel and training records (internal and external training courses)

## Objective evidence assessed / Observations / Comments / N/A explanation

Keith Lessner - engineer (MELPHI) Lead Thermal Eng.

D. Clark - 7/2 - 6/3

IDP - Ind. Dev. Plan - 40-80 hrs training -

Observed Infrastructure management - posting of Bldg Managers.

Contractor performance for facilities

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management



## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 6. RESOURCE MANAGEMENT

## 6.1 Provision of resources

- 01 Has the organization determined and provided the resources needed:
- a) to implement and maintain the quality management system and continually improve its effectiveness? And
  - b) to enhance customer satisfaction by meeting customer requirements?

## 6.2 Human resources

## 6.2.1 General

- 02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1)?

## 6.2.2 Competence, awareness and training

- 03 Does the organization:
- a) determine the necessary competence for personnel performing work affecting product quality (2)?
  - b) provide training or take other actions to satisfy these needs? -
  - c) Evaluate the effectiveness of the actions taken? -
  - d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? -
  - e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3)?

## 6.3 Infrastructure

- 04 Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements?
- Infrastructure includes, as applicable:

- a) buildings, workspace and associated utilities?
- b) process equipment (both hardware and software)?
- c) supporting services (such as transport or communication)?

## 6.4 Work environment

- 05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements?

**Note:** Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

## Guidance Notes

- 1) Review training Records and Plan (status of the current year and of the previous year)-
- 2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill, ...)
- 3) Review training certificates for the certified personnel and training records (internal and external training courses)

## Objective evidence assessed / Observations / Comments / N/A explanation

Received Processes for performance evaluation, Directorate records of training, Process for identifying skill sets interfaces with facilities management. Directorate audits of work environment for safety and resource needs.

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7. PRODUCT REALIZATION

## 7.1 Planning of product realization

01 Does the organization plan and develop the processes needed for product realization ? (see 4.1) <i>yes</i>		S			
02 Is planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1) ?		S			
03 In planning product realization, does the organization determine the following, as appropriate : a) quality objectives and requirements for the product ? b) the need to establish processes, documents, and provide resources specific to the product ? c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance ? d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ? e) <i>the identification of resources to support operation and maintenance of the product ?</i>	P	S			
04 Is the output of this planning in a form suitable for the organization's method of operations?		S			

## Objective evidence assessed / Observations / Comments / N/A explanation

MSG - Subrite payloads integration and operations Service  
Integration Process document. MSFC Plan 3052.  
Technical Interchange Meeting, IR data Collection. Integration  
data Interface Control document. Integration review  
Command and data, Payload Library Input. Flight  
Certification process, Certification flight readiness review.  
MSFC ST 52054. Ref table E-1 COFR; launch, on-orbit, return.  
Endorsement table, Table E-1 COFR payloads office endorsement  
Content. HW & SW ICDs, payload verification plan  
Crew operating Procedure, Safety Process, On-Orbit crew  
Procedures and/or ground, Schedule

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.2 Customer-related processes

## 7.2.1 Determination of requirements related to the product

05 Does the organization determine :

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities ?
- b) requirements not stated by the customer but necessary for specified or intended use, where known ?
- c) statutory and regulatory requirements related to the product ? and
- d) any additional requirements determined by the organization ?

M

✓

## 7.2.2 Review of requirements related to the product

06 Does the organization review the requirements related to the product ?

✓

07 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that (1) :

P

- a) product requirements are defined ?
- b) contract or order requirements differing from those previously expressed are resolved ?
- c) the organization has the ability to meet the defined requirements ? And
- d) risks (e.g., new technology, short delivery time scale) have been evaluated ?

✓

08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2) ?

✓

09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance ?

✓

10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements ?

P

✓

Note : In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover the relevant product information such as catalogues or advertising material.

## 7.2.3 Customer communication

11 Does the organization determine and implement effective arrangements for communicating with customers in relation to :

- a) product information ?
- b) enquiries, contracts or order handling, including amendments ? and
- c) customer feedback, including customer complaints ?

✓

## Guidance Notes

- 1) Check that all affected functions are involved in the review
- 2) Give examples

## Objective evidence assessed / Observations / Comments / N/A explanation

Facility Project - Build Project Document  
Proj # 6765

② PRL facility - Reviewed Contract activities  
Customer communication

② ECLSS program  
water recovery -  
Regts - SRPR, Contract records

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.3 Design and development

## 7.3.1 Design and development planning

NRG 8823-1

12 Does the organization plan and control the design and development of product ?		✓			
13 During the design and development planning, does the organization determine : a) the design and development stages (1) ? - <i>in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,</i> b) the review, verification and validation that are appropriate to each design and development stage ? and c) the responsibilities and authorities for design and development ?	M	✓			
14 Where appropriate, due to complexity, does the organization give consideration to the following activities : - <i>structuring the design effort into significant elements ?</i> - <i>for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements ?</i>		✓			
15 Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility ?		✓			
16 Is planning output updated, as appropriate, as the design and development progresses ?		✓			
17 Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements (2) ?	P	✓			

7.3.2 Design and development inputs

18 Are inputs relating to product requirements determined and are records maintained (see 4.2.4) (3) ? Do these inputs include : a) functional and performance requirements ? b) applicable statutory and regulatory requirements ? c) where applicable, information derived from previous similar designs ? and d) other requirements essential for design and development ?	M	✓			
19 Are these inputs reviewed for adequacy ?		✓			
20 Are requirements completed, unambiguous and not in conflict with each other ?		✓			

## Guidance Notes

- 1) Give at least an example of a completed design & development plan, or an example of one in progress, that identifies the planning of tasks and key events.
- 2) Give an example
- 3) Review applicable input data (give examples)

## Objective evidence assessed / Observations / Comments / N/A explanation

Facility Project - Brief Proj. Document Form 1509 #22M. Code 6765  
 Facility Proj. Cost Estimate Form 1570  
 Project Reg's Document - Prop. Research Lab. June 00  
 Design Phases - documented on spread sheet as of 30/40/90/final reviews

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
 N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

Thurs 050

Jim Lindsay

ECLSS - water recovery, oxygen generation

wkly mtgs

verification/validation phase

SRR - } project office has records of review  
PDR - }  
CDR - }

David Whitten  
Thurs 2:00

Structural Design - ED23-OWI-001 Rev C

OGS Project (Oxygen Generation System)

↳ Requirement Review -

Project Plan - ECLSS-FD21-009 - Basic 7/10/01

Des. Review - PDR/CDR documented on ECLSS/FD-21 Web Site

Integrated Rack + Uline process - CDR 3/24-5/15/02

Verification

EER → EO as per SDA 555

EER#

ED23-2647

EO#

1

P/N

96M11546-1

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.3 Design and development (continued)

## 7.3.3 Design and development outputs

21 Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release ?

✓

22 Do the design and development outputs :

- a) meet the input requirements for design and development ?
- b) provide appropriate information for purchasing, production and for service provision ?
- c) contain or reference product acceptance criteria ?
- d) specify the characteristics of the product that are essential for its safe and proper use ? and
- e) *identify key characteristics, when applicable, in accordance with design or contract requirements ?*

M

✓

23 Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization; for example:

- drawings, part lists, specifications ?
- a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product ?
- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product ?

M

✓

## 7.3.4 Design and development review

24 At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to (1) :

- a) evaluate the ability of the results of Design and development to meet requirements ?
- b) identify any problems and propose necessary actions ? and
- c) *authorize progression to the next stage ?*

M

✓

25 Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed ?

✓

26 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?

✓

## 7.3.5 Design and development verification

27 Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements ?

✓

28 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?

✓

**Note :** Design and/or development verification may include activities such as :

- performing alternative calculations
- comparing the new design with a similar proven design, if available
- undertaking tests and demonstrations, and
- reviewing the design stage documents before release.

## Guidance Notes

- 1) Give evidence of reviews

## Objective evidence assessed / Observations / Comments / N/A explanation

Des Review - 40% 12/7/01  
30% 9/7/01  
90%

Outputs - Dwg FAC M4199  
Construction Spec. Appr

Base building - FAC-A-4205-G001

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 7.3 Design and development (continued)

## 7.3.6 Design and development validation

29	Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known ?	P	/			
30	Wherever practicable, is validation completed prior to the delivery or implementation of the Product ?		/			
31	Are records of the results of validation and any necessary actions maintained (see 4.2.4) ?		/			

## Note:

- Design and/or development validation follows successful design and/or development verification.
- Validation is normally performed under operating conditions.
- Validation is normally performed on the final product, but may be necessary in the earlier stages prior to product completion.
- Multiple validations may be performed if there are different intended uses.

## 7.3.6.1 Documentation of design and/or development verification and validation

32	At the completion of design and/or development, does the organization ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions?	M	✓			
----	--	---	---	--	--	--

## 7.3.6.2 Design and/or development verification and validation testing

33	Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following (1) : a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria ? b) test procedures describe the method of operation, the performance of the test, and the recording of the results ? c) the correct configuration standard of the product is submitted for the test ? d) the requirements of the test plan and the test procedures are observed ? e) the acceptance criteria are met ?	P	✓			
----	---	---	---	--	--	--

## Guidance Note

- 1) Give an example of a qualification report

## Objective evidence assessed / Observations / Comments / N/A explanation

See previous 2 pages for programs - ECLSS pgm  
E023-OWF 001 - Structural Des.  
Verified Validation of Drawings -

## QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

## 7.3 Design and development (continued)

## 7.3.7 Control of design and development changes

34	Are design and development changes identified and records maintained ?		✓		
35	Are the changes reviewed, verified and validated, as appropriate, and approved before implementation (1) ?	P	✓		
36	Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered ?	P	✓		
37	Does the organization's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement ?		✓		
38	Records of the results of the review of changes and any necessary actions maintained (see 4.2.4) ?		✓		

## Guidance Note

1) Give an example

## Objective evidence assessed / Observations / Comments / N/A explanation

ECR#	EO#	DWG# PN#
ED23-2657	1	96411514-1
ED23-2647	1	96411546-1

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
 N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management



## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 7.4 Purchasing

## 7.4.1 Purchasing process

39	Does the organization ensure that purchased product conforms to specified purchase Requirements ?	P	S			
40	Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product ?		mi mi			
41	Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources ? <i>yes</i>		S			
42	Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements ? <i>yes major Acquisition / no</i>		mi mi			
43	Are criteria for selection, evaluation and re-evaluation established ? <i>by Validation for each contract</i>					
44	Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4) ? <i>Records are maintained SQA org</i>		S			
45	Does the organization :	M	S			
a)	Maintain a register of approved Suppliers that includes the scope of the approval (1) ? <i>yes</i>					
b)	Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented (2) ? <i>in major acquisition</i>					
c)	Define the necessary actions to take when dealing with Suppliers that do not meet requirements ? <i>in contract</i>					
d)	Ensure where required that both the organization and all Suppliers use customer-approved special process sources ? <i>N/A</i>					✓
e)	Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources ? <i>yes per contract</i>		S			

## Guidance Notes

- Review current list of approved Suppliers *reviewed*
- Review suppliers performance / measurement system (e.g.: supplier rating, etc.) *Performance criteria identified with subsequent action*

## Objective evidence assessed / Observations / Comments / N/A explanation

Vendor Audits *MWIF 5330.1, Capability, and QMS ISO 9001.*  
 Initial assessment, monitor performance; quality.  
 Verified Barber Nichols, Sierra Lobo, Metalex. *Redudit every 3yrs.*  
 AVL verified. Reviewed Audits of suppliers: Metalex dated  
 2/18/04 Still auditing ISO 9001:1994.  
 Acquisition Strategy is determined prior to Delimitation  
 Mission Sustainability requirements, Scored factor, past performance  
 Evaluation Riddle, FAR PART 15 or 12, NASA FAR supplement Part 14  
 Quality Requirements, Safety Requirement, Subcontract Requirements  
 FAR PART 44. Extent of control/qualification varies by extent of technical  
 requirements associated with product type. COF tracks performance  
 Contract Surveillance, Performance reports, COF data requirements  
 Fed Acquisition Principles/Requirements. Contract NAS 8-01140  
 Procedure does not address qualification, performance criteria,  
 consequences of past performance. Actions when potential  
 risk is identified during Supplier Audit not identified.

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 N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.4 Purchasing (continued)

## 7.4.2 Purchasing information

<p>46 Does purchasing information describe the product to be purchased, including where appropriate (1) :</p> <p>a) requirements for approval of product, procedures, processes and equipment ? <i>yes</i></p> <p>b) requirements for qualification of personnel ?</p> <p>c) quality management system requirements ?</p> <p>d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data ?</p> <p>e) requirements for design, test, examination, inspection and related instructions for acceptance by the Organization ?</p> <p>f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing ?</p> <p>g) requirements relative to :</p> <ul style="list-style-type: none"> <li>- supplier notification to Organization of nonconforming product ? and</li> <li>- arrangements for Organization approval of supplier nonconforming material ?</li> </ul> <p>h) requirements for the supplier to notify the Organization of changes in product and/or process definition and, where required, obtain organization approval ?</p> <p>i) right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records ? and <i>yes</i></p> <p>j) requirements for the supplier to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required ? <i>yes</i></p>	<p>P</p> <p>S</p> <p>S</p>		
<p>47 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier ? <i>yes</i></p>	<p>S</p>		

## Guidance Note

- 1) Examine purchase orders that apply to several types of procurement.

*Engineering Services, main engine*

## Objective evidence assessed / Observations / Comments / N/A explanation

*SOW, data requirements, award fee, Make or buy plan  
SB, Provided Property, applicable regulations, Jack direction flow  
work breakdown, SD 254 Contract Security Contract # NAS 8-00187  
Source inspection, right of entry, and per Fed Acquisition  
requirements. Reviewed purchase orders ref:  
Hamilton Standard PO FH151-04, 2 Miller, Arrow Electric  
PONAS 8-98053, NAS 8-01140*

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N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.4 Purchasing (continued)

## 7.4.3 Verification of purchased product

48 Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification? <i>yes</i>	P	S			
49 Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure? <i>yes</i>		S			
50 Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications (1)? <i>yes</i>		S			
51 Does the organization periodically validate test reports for raw material (1)? <i>yes</i>		S			
52 Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained (1)?		S			
53 Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of product release in the purchasing information?		S			
54 Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements?		S			
55 It is ensured that verification by the customer is not used by the organization as evidence of effective control of quality by the supplier (it does not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer)?		S			

## Guidance Note

1) Give an example *P/N PNC55H90R9FS, R280 222 000, SV825500-1 5/Nov001*

Objective evidence assessed / Observations / Comments / N/A explanation

*Inspection Acceptance Record #04347, 04348*  
*Detailed instruction with each receiver*  
*Periodic testing of raw materials*  
*IAR 4224 606PT6, 303, 416*

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 N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 7.5 Production and service provision

## 7.5.1 Control of production and service provision

56 Does planning consider, as applicable :

- the establishment of process controls and development of control plans where key characteristics have been identified *Min Science objectives*
- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization *Constant monitoring*
- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- special processes (see 7.5.2). *Test requirements translated to development of test procedure*

57 Does the organization plan and carry out production and service provision under controlled conditions (1). *yes*

Do these controlled conditions include, as applicable :

- a) the availability of information that describes the characteristics of the product? *Test procedures*
- b) the availability of work instructions, as necessary? *yes*
- c) the use of suitable equipment? *Payload Risk Checkpoint unit.*
- d) the availability and use of monitoring and measuring devices? *yes*
- e) the implementation of monitoring and measurement? *yes*
- f) the implementation of release, delivery and post-delivery activities? *yes*
- g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)? *Part Markings & Serialisation*
- h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized? *Test Plan*
- i) provision for the prevention, detection, and removal of foreign objects? *Built into process*
- j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality? *yes*
- k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)? *yes*

## Guidance Notes

- 1) List the Part Number(s) used for this review *On-orbit operations, MSG Integration Survey*

Objective evidence assessed / Observations / Comments / N/A explanation

*Payload operations Monitoring.*  
 MSG Plan 002, IR Plan Microgravity Science Gluebox 9/30/03  
 Contract NAS8-02060 Integration Review 10/16/03, 10/16/03 Kickoff  
 10/16-24/03 Revue Review, 10/24/03 RIDs due to MSG IPIM, 10/28/03 RIDs response  
 10/29/03 Review Committee mtg - MSFC-RQMT-2888, MSFC Plan 3052  
 MSFC-HDBK-3051, ESA Argos Documentation Integration Schedule  
 DSM Integration Review 11/5/03, CFR, FCR 3/1/04.  
 ICD-MSFC-ICD-3270; MGUEMSGSPCEN001.

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 N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or ml	N/A	N/E
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## 7.5 Production and service provision (continued)

## 7.5.1.1 Production documentation

58 Are production operations carried out in accordance with approved data ?	<i>yes</i>		<i>3</i>		
59 Does the data contain as necessary : a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1) ? and b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use ?	<i>yes</i> <i>no NC machines</i>	P	<i>3</i> <i>5</i>		

## 7.5.1.2 Control of production process changes

60 Are persons authorized to approve changes to production processes identified (1) ?	<i>yes</i>	M	<i>5</i>		
61 Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements ?	<i>yes</i>		<i>5</i>		
62 Are changes affecting processes, production equipment, tools and programs documented ?		P	<i>5</i>		
63 Are procedures available to control their implementation ?	<i>yes</i>		<i>5</i>		
64 Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality ?	<i>yes</i>	P	<i>5</i>		

## 7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs

65 Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures ?	P				<i>✓</i>
66 Does validation prior to production use include verification of the first article produced to the design data/specification ?	P				<i>✓</i>
67 Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage ?					<i>✓</i>

## 7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities

68 When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work ?	M				<i>✓</i>
---	---	--	--	--	----------

## Guidance Notes

- 1) Clearly defined list or procedures *identified by released lists.*

## Objective evidence assessed / Observations / Comments / N/A explanation

*Best procedures in place ref: SPICE  
Changes are controlled, routine process in place.*

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - ml: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.5 Production and service provision (continued)

## 7.5.1.5 Control of service operations

- 69 Where servicing is a specified requirement, do service operation processes provide for :
- a method of collecting and analyzing In-service data ?
  - actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2) ?
  - the control and updating of technical documentation ?
  - the approval, control, and use of repair schemes (3) ? and,
  - the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities) ?

## 7.5.2 Validation of processes for production and service provision

- 70 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered) (4) ?

**Note :** These processes are frequently referred to as special processes.

- 71 Does validation demonstrate the ability of these processes to achieve planned results ?

- 72 Has the organization established arrangements for these processes including, as applicable :

- defined criteria for review and approval of the processes ?  
-qualification and approval of special processes prior to use ?
- approval of equipment and qualification of personnel ?
- use of specific methods and procedures ?  
- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?
- requirements for records (see 4.2.4) ?
- and revalidation ?

## Guidance Notes

- Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports
- Review evidence of implementation of corrective and preventive actions.
- Review evidence of what has been assessed ( e.g.: maintenance manual, repair manual, information to customer)
- Verify the existence of list of special processes.
- Give examples

## Objective evidence assessed / Observations / Comments / N/A explanation

7.5.2 Not applicable to Programs Audited During this visit.  
7.5.1.5 Not applicable to Programs Audited.

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 7.5 Production and service provision (continued)

## 7.5.1.5 Control of service operations

- 69 Where servicing is a specified requirement, do service operation processes provide for :
- a method of collecting and analyzing in-service data ?
  - actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2) ?
  - the control and updating of technical documentation ?
  - the approval, control, and use of repair schemes (3) ? and,
  - the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities) ?

✓

## 7.5.2 Validation of processes for production and service provision

- 70 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered) (4) ?

P

✓

**Note :** These processes are frequently referred to as special processes.

*No Samples found*

- 71 Does validation demonstrate the ability of these processes to achieve planned results ? *No Sample*

✓

- 72 Has the organization established arrangements for these processes including, as applicable :

M

✓

- defined criteria for review and approval of the processes ?  
-qualification and approval of special processes prior to use ?
- approval of equipment and qualification of personnel ?
- use of specific methods and procedures ?  
- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?
- requirements for records (see 4.2.4) ?
- and revalidation ?

*No Samples found*

## Guidance Notes

- Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports
- Review evidence of implementation of corrective and preventive actions.
- Review evidence of what has been assessed ( e.g.: maintenance manual, repair manual, information to customer)
- Verify the existence of list of special processes.
- Give examples

## Objective evidence assessed / Observations / Comments / N/A explanation

*No evidence of special processes*

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N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management



## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.5 Production and service provision (continued)

## 7.5.3 Identification and traceability

- 73 Where appropriate, has the organization identified the product by suitable means throughout product realization? *yes*
- 74 Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration? *P*
- 75 Has the organization identified the product status with respect to monitoring and measurement requirements? *MPS 8730.2*
- 76 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1)? *S*
- 77 Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4)? *TPS or TOP*
- 78 According to the level of traceability required by contract, regulatory, or other established requirement, does the organization's system provide for (2): *P*
- a) identification to be maintained throughout the product life? *P/N/S/N*
  - b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch?
  - c) in any assembly, the identity of its components and those of the next higher assembly to be traced?
  - d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved?

Note: In some industry sectors, configuration management is a means by which identification and traceability is maintained.

## 7.5.4 Customer property

- 79 Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (3)? *yes*
- 80 Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product? *yes*
- 81 Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer? *no*

Note: Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection.

## Guidance Notes

- 1) Give examples of method(s) used *Tag, Part Inspection Stamps*
- 2) Give examples of traceability level applied (up and down) - *P/N Serial number*
- 3) Identify types of product supplied by the customer. *Flight assemblies for test*

## Objective evidence assessed / Observations / Comments / N/A explanation

*CSP tag is utilized to track and ID & trace is recorded on tag.*

*940*

*Stamps: Quality, Safety ref 340, yearly Stamp Audit*

*Lost or terminated bond procedure. Reviewed database*

*and Stamp inventory. When: issue Stamp, lost Stamp, turn in Stamp,*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.5 Production and service provision (continued)

## 7.5.3 Identification and traceability

73	Where appropriate, has the organization identified the product by suitable means throughout product realization ?		✓			
74	Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration ?	P	✓			
75	Has the organization identified the product status with respect to monitoring and measurement requirements ?		✓			
76	When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1) ?		✓			
77	Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4) ?		✓			
78	According to the level of traceability required by contract, regulatory, or other established requirement, does the organization's system provide for (2) : a) identification to be maintained throughout the product life ? b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch ? c) in any assembly, the identity of its components and those of the next higher assembly to be traced ? d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved ?	P	✓			

Note: In some industry sectors, configuration management is a means by which identification and traceability is maintained.

## 7.5.4 Customer property

79	Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (3) ?		✓			
80	Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product ?		✓			
81	Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer ?		✓			

Note: Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection.

## Guidance Notes

- 1) Give examples of method(s) used
- 2) Give examples of traceability level applied (up and down)
- 3) Identify types of product supplied by the customer.

## Objective evidence assessed / Observations / Comments / N/A explanation

7.5.3 - Product - output of analysis - reports - Test results identified as to part # & document # along with status of same

7.5.4. Documents - proprietary. Syst. Qual. Review - Alienia - CLT-EQ-AI-0007  
numerous documents maintained in locked room  
MPLM Drawing

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.5 Production and service provision (continued)

## 7.5.5 Preservation of product

82	Does the organization preserve the conformity of product during internal processing and delivery to the intended destination ?		S			
83	Does the preservation include identification, handling, packaging, storage and protection ?		S			
84	Does preservation also apply to the constituent parts of a product ?		S			
85	Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for : a) cleaning ? b) prevention, detection and removal of foreign objects ? c) special handling for sensitive products ? d) marking and labeling including safety warnings ? e) shelf life control and stock rotation ? f) special handling for hazardous materials ?	P				
86	Does the organization ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration ?		S			

## Objective evidence assessed / Observations / Comments / N/A explanation

Flight Standards followed. Observed assemblies in Test Areas. Articles are appropriately protected. ESD program in place. Special handling of flight hardware.  
 Rq P/N 96M H900-1-105-900, 96M13153-1-106

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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7.6 Control of monitoring and measuring devices *MFG 8730.5*

87 Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1) (1)? <i>yes</i>	P	S			
88 Does the organization maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria? <i>revised list/diase</i> <i>Note: Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.</i>	M	S			
89 Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements? <i>yes</i>		S			
90 Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out? <i>verified environmental</i>		S			
91 Where necessary to ensure valid results, is measuring equipment: a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (2)? <i>yes</i> b) adjusted or re-adjusted as necessary? <i>yes</i> c) identified to enable the calibration status to be determined? <i>yes</i> d) safeguarded from adjustments that would invalidate the measurement result? <i>was protected</i> e) protected from damage and deterioration during handling, maintenance and storage? <i>protected</i> f) recalled to a defined method when requiring calibration? <i>yes</i>		S			
92 Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements? <i>yes</i>		S			
93 Does the organization take appropriate action on the equipment and any product affected? <i>yes</i>	P	S			
94 Are records of the results of calibration and verification maintained (see 4.2.4)? <i>yes</i>		S			
95 When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed? <i>yes</i>	P	S			
96 Is this undertaken prior to initial use and reconfirmed as necessary? <i>yes</i>		S			

## Guidance Notes

*Meters only Cal as needed*

- Review that the organization has a process for ensuring the capability of measurement system (e.g. Interval Analysis, Resolution Analysis, Gage Repeatable & Reproducibility, etc.) *yes*
- Ensure the links to the recognized international / national standard. *Traceable to NIST*

## Objective evidence assessed / Observations / Comments / N/A explanation

*Verified status of 090004, M629829, M620113, M635577, M631229, M633677 in data base.*  
*Monthly recall list published via email, recall report*  
*Cal Procedure 2-0039: Plug gage, 2-0049: Pressure Gage*  
*Items have identifying number, tag on instruments*  
*indicate status/Cal date. Disposition report utilized for out of*  
*tolerance equipment. Notification to owner*  
*Temp & humidity recorders in building and labs. Verified availability*  
*1-0580 procedure in lab. 1-0270 oscilloscope, Thread gages, Plug gages*  
*Multimeters,*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General *TD 70-08 Planning Document.*

01 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed (1):

M

S

a) to demonstrate conformity of the product

*Test Process*

b) to ensure conformity of the quality management system, and ?

*following process updating OI's*

c) to continually improve the effectiveness of the quality management system ?

S

02 Does this include determination of applicable methods, including statistical techniques, and the extent of their use ?

S

**Note :** According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support :

-design verification (e.g., reliability, maintainability, safety) ;

-process control :

• selection and inspection of key characteristics;

• process capability measurements;

• statistical process control; -

• design of experiment; -

-inspection - matching sampling rate to the criticality of the product and to the process capability ;

-failure mode and effect analysis.

## Guidance Notes

1) Give examples of data

*Test Requirement 5.7, 4/1/2003, Environmental Engineering Pollution Plan 3/04*Objective evidence assessed / Observations / Comments / N/A explanation *also 8.2.4 -*

*Test Service organization Transportation Directorate Safety and Mission Assurance Test operation Support are all involved in planning. TD 73 Standard process is utilized to plan. Test document identifies requirements i.e. test matrix, test parameters Facility operating Procedures, test Checklist Procedures. Test preparation sheets are utilized, TD 70-004 Test Procedure Instructions, Mandate of inspection points utilized to enforce compliance, to processes and systems. measurement test.*

*Environmental Pollution Prevention Plan Update 3/04 During new product planning EPA issues are evaluated as part of test readiness review.*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 8.2 Monitoring and measurement (continued)

## 8.2.1 Customer satisfaction

03 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements (1) ?

✓

04 Are the methods for obtaining and using this information determined?

✓

## 8.2.2 Internal audit

MPG 1280.6 Rev E

05 Does the organization conduct internal audits at planned intervals to determine whether the quality management system (2) :

M

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization? and

NC

Carry over

b) is effectively implemented and maintained?

06 Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?

✓

07 Is the audit criteria, scope, frequency and methods defined?

✓

08 Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process (3) ?

✓

09 Does the organization ensure internal auditors do not audit their own work ?

✓

10 Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure ?

✓

11 Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes ?

M

✓

12 Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2) (4) ?

✓

13 Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements ?

✓

14 Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organization performance ?

✓

15 Do internal audits also meet contract and/or regulatory requirements ?

✓

## Guidance Notes

- 1) Give examples of how customer's satisfaction is measured, committed, and acted upon.
- 2) Review of audit plan (status of the previous year and progress of the current year).
- 3) Check the list of approved auditors.
- 4) Review type of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective actions follow-up).

## Objective evidence assessed / Observations / Comments / N/A explanation

Audits scheduled - Auditor objectivity + independence

Audit # ED 05200401 -

PS 02200401 - obs, obs. concerns, NC's - Reviewed Audit Report  
NC #605

Evidence of customer satisfaction provided at mgmt Review - Bel. scorecard

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 8.2 Monitoring and measurement (continued)

## 8.2.3 Monitoring and measurement of processes

16 Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes? *Test input/output and*

S

17 Do these methods demonstrate the ability of the processes to achieve planned results? *yes EDA/ED*

S

18 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product? *treat as nonconformance*

S

19 In the event of process nonconformity, does the organization (1):

P

S

a) take appropriate action to correct the nonconforming process? *yes*b) evaluate whether the process nonconformity has resulted in product nonconformity? *yes*

S

c) identify and control the nonconforming product in accordance with clause 8.3?

S

## 8.2.4 Monitoring and measurement of product

20 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met? *yes*

P

S

21 Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1)? *yes MEP*

S

22 When key characteristics have been identified, are they monitored and controlled?

P

S

23 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use? *yes*

S

24 Does the plan preclude the acceptance of lots whose samples have known nonconformities? *yes*

S

25 When required, is the plan submitted for customer approval? *yes*

S

26 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities? *yes*

P

S

27 Is evidence of conformity with the acceptance criteria maintained? *yes*

S

28 Do records indicate the person(s) authorizing release of product (see 4.2.4)? *yes*

S

29 Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer? *yes*

S

## Guidance Note

1) Give examples of non conformity (product, process, ...). *Test process, Chlorine leak*

## Objective evidence assessed / Observations / Comments / N/A explanation

*Root Analysis to ensure parameters of process is achieved*  
*QTPS utilized for nonconformances. Root test and structural*  
*Hydraulic Test Series Test Request. Cryo Structural Test Conditions*  
*RF STF TCPO06, STF-FOP-016 Control Systems, STF-FOP-08 Cutoff Checks*  
*STF FOP-017 Instrumentation, STF-FOP-014 Mechanical Systems*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 8.2 Monitoring and measurement (continued)

## 8.2.4.1 Inspection documentation

also See 8.2.4 MFG 8730.2

30 Are measurement requirements for product or service acceptance documented?

S

31 Does this documentation, which may be part of the production documentation, include:

P

- a) Criteria for acceptance and/or rejection? *yes Test*
- b) Where in the sequence measurement and testing operations are performed? *MIP*
- c) a record of the measurement results? and *yes renewed*
- d) type of measurement instruments required and any specific instructions associated with their use? *Instruments*

S

32 Do test records show actual test results data when required by the specification or acceptance test plan?

*yes as applicable*

S

33 When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements?

S

## 8.2.4.2 First article inspection

*Proof Test*

34 Does the organization's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result (1)?

*yes Extensive documentation yes*

P

S

## Guidance Note

1) Give examples of first article (new product and change).

*SPICE, 96M11900-1-105,*

Objective evidence assessed / Observations / Comments / N/A explanation

*Technology Proof of Concept. See notes pg. 42*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

8.3 Control of nonconforming product *TD 70007***Note:** The term "nonconforming product" includes nonconforming product returned from a customer.

35 Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery ?	P	S			
36 Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure ?		S			
37 Does the organization's documented procedure define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions ?		S			
38 Does the organization deal with nonconforming product in one or more of the following ways by: a) taking action to eliminate the detected nonconformity ? b) authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer ? c) taking action to preclude its original intended use or application ?	P	S			
39 Does the organization prevent disposition of use-as-is or repair, unless specifically authorized by the customer, if - the product is produced to customer design ? or - the nonconformity results in a departure from the contract requirements ? (Unless otherwise restricted in the contract, is organization-designed product, which is controlled via a customer specification, dispositioned by the organization as-use-as is or repair, provided the nonconformity does not result in a departure from customer-specified requirements ?)		S			
40 Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable ?	P	S			
41 Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained. (see 4.2.4) ?		S			
42 When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements ?		S			
43 When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity ?	P	S			
44 In addition to any contract or regulatory authority reporting requirements, does the organization's system provide for timely reporting of delivered nonconforming product that may affect reliability or safety ?	P	S			
45 Does notification include a clear description of the nonconformity, which includes as necessary, parts affected, customer and/or organization part numbers, quantity, and date(s) delivered ?		S			

Objective evidence assessed / Observations / Comments / N/A explanation

*QTPS is utilized to document nonconformance. Withhold tags. QTPS is test constraint. Ref TPS-STF 1440-QM: TD 17725, STF 1469-QC: TD 017965 - STF-1440-Q7: TD 017981. Ref discharge: DSN001 3/25/03 and back-up analytical data. Containment for expenditure by Clarence Insight unit, Integrated Testing unit, training & ground unit. nonconformance Process 8430.3. Received TDR Log and TDR 001, 002, 003 Fabricated Product Discrepancy record, TDR & DR Ref DR 7366, 7273, 7315, 7259, SLIDR 0002029, 0002084, 0002112, 7361, 7362, 7363*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 8.4 Analysis of data

46 Does the organization determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made ?	M	✓			
47 Does this include data generated as a result of monitoring and measurement and from other relevant sources ?		✓			
48 Does the analysis of data provide information relating to : a) customer satisfaction (see 8.2.1) (1) ? b) conformity to product requirements (see 7.2.1) ? c) characteristics and trends of processes and products including opportunities for preventive action ? And d) suppliers ?		✓			

## Guidance Note

- 1) Give examples and check how the organization measures the effectiveness.

## Objective evidence assessed / Observations / Comments / N/A explanation

*Observed data analysis - evidenced in Balanced Scorecard measure  
at management review dated 5/25/04*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 8.5 Improvement

## 8.5.1 Continual improvement

49 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review ?

## 8.5.2 Corrective action

50 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence (1) ? *yes Extensive evaluation*

P

51 Are Corrective actions appropriate to the effects of the nonconformities encountered ?

52 Is a documented procedure established to define requirements for :

- a) reviewing nonconformities (including customer complaints) ?
- b) determining the causes of nonconformities ? *yes*
- c) evaluating the need for action to ensure that nonconformities do not recur ?
- d) determining and implementing action needed ?
- e) recording of the results of the action taken (see 4.2.4) ? *yes DR*
- f) reviewing corrective action taken ? *yes*

g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause ? and *FAP PART 49 NASA Supplement is part of contract*

h) specific actions where timely and/or effective corrective actions are not achieved ? *See notes*

## 8.5.3 Preventive action

53 Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence (2) ?

M

54 Are preventive actions appropriate to the effects of the potential problems ?

55 Is a documented procedure established to define requirements for :

- a) determining potential nonconformities and their causes ?
- b) evaluating the need for action to prevent occurrence of nonconformities ?
- c) determining and implementing action needed ?
- d) recording of the results of the action taken (see 4.2.4) ? and
- e) reviewing preventive action taken ?

## Guidance Notes

- 1) Select a non-conforming part and use 52 a) through h) to check for effectiveness.
- 2) Select a non-conforming part and use 55 a) through e) to check for effectiveness.

*96M1900-1-105-900, 96M13531-10*  
*DR 7366*  
*DR 7273 SPICE DEV*

## Objective evidence assessed / Observations / Comments / N/A explanation

*QTPS disposition, root cause analysis*

*Reviewed Corrective Actions records & responses follow up actions.*

*\*Supplier Corrective Actions do not address RCA.*

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## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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## 8.5 Improvement

## 8.5.1 Continual improvement

49 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review ?

✓

## 8.5.2 Corrective action

50 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence (1) ?

P

51 Are Corrective actions appropriate to the effects of the nonconformities encountered ?

52 Is a documented procedure established to define requirements for :

- a) reviewing nonconformities (including customer complaints) ?
- b) determining the causes of nonconformities ?
- c) evaluating the need for action to ensure that nonconformities do not recur ?
- d) determining and implementing action needed ?
- e) recording of the results of the action taken (see 4.2.4) ?
- f) reviewing corrective action taken ?
- g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause ? and
- h) specific actions where timely and/or effective corrective actions are not achieved ?

## 8.5.3 Preventive action

53 Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence (2) ?

M

54 Are preventive actions appropriate to the effects of the potential problems ?

55 Is a documented procedure established to define requirements for :

- a) determining potential nonconformities and their causes ?
- b) evaluating the need for action to prevent occurrence of nonconformities ?
- c) determining and implementing action needed ?
- d) recording of the results of the action taken (see 4.2.4) ? and
- e) reviewing preventive action taken ?

## Guidance Notes

- 1) Select a non-conforming part and use 52 a) through h) to check for effectiveness.
- 2) Select a non-conforming part and use 55 a) through e) to check for effectiveness.

## Objective evidence assessed / Observations / Comments / N/A explanation

individual improvement initiatives - 04-04-20, May '04, noted on Log (113 total)

Preventive action evidenced at management Review, dated 5/25/04

Risk Management - Fleet Activities.

Safety activities, reported on at MTM - QD 50  
yellow, green health, Safety metrics

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N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

{ Sustaining Eng. Plan.  
ISS- MPLM-PLAN-015 Rev A

REN: MA1633124

MWI 8040.2

Obs. 4619

Air Quality Sample - record - Tags

**Annex A**  
**(informative)**

**Bibliography**

ISO 9000: 2000	Quality management systems – Fundamentals and vocabulary
ISO 9001: 2000	Quality management systems – Requirements
ISO 10011	Guidelines for auditing quality systems
EN 9100 – Section 1	Aerospace series – Quality management systems – Requirements (based on ISO 9001: 2000)



## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.5 Production and service provision

## 7.5.1 Control of production and service provision

56 Does planning consider, as applicable :

- the establishment of process controls and development of control plans where key characteristics have been identified
- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization
- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- special processes (see 7.5.2).

P

✓

57 Does the organization plan and carry out production and service provision under controlled conditions (1).

Do these controlled conditions include, as applicable :

- a) the availability of information that describes the characteristics of the product ? ✓
- b) the availability of work instructions, as necessary ? ✓
- c) the use of suitable equipment ? ✓
- d) the availability and use of monitoring and measuring devices ? ✓
- e) the implementation of monitoring and measurement ? ✓
- f) the implementation of release, delivery and post-delivery activities ? ✓
- g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product) ? ✓
- h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized ? ✓
- i) provision for the prevention, detection, and removal of foreign objects ? ✓
- j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality ? and
- k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations) ? ✓

P

P

✓

Obs

49

## Guidance Notes

1) List the Part Number(s) used for this review

## Objective evidence assessed / Observations / Comments / N/A explanation

ISS. Change Request SSCN-8692 - change evaluation form

PIRD # 57212 - NA-0029A MELFI Hardware CD Post-Rev B  
evaluation performed and response documented

Eng. Recommendation - K. Presson

Test Rec. # MTCR-FS-MPLM PT-303 10/28/03 Basic ✓ Current  
Vacuum chamber -  
calibrated devices testedS: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: ManagementPressure gauges - 5yr cal cpl - operational check cal dt 5/98 - 5/03 (5y ago)  
might be confusing

{ Sustaining Eng. Plan.  
ISS- MPLM-PLAN-015 Rev A

REN : MA 1633124

MWI 8040.2

Qty. 4619

Air Quality Sample - record - Tags



## QUALITY SYSTEM QUESTIONNAIRE

## ASSESSMENT QUESTIONS

KEY  
Requirements

S

CAR  
Number  
Ma or mi

N/A

N/E

## 7.5 Production and service provision (continued)

## 7.5.1.1 Production documentation

58 Are production operations carried out in accordance with approved data ?

59 Does the data contain as necessary :

- a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1) ? and
- b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use ?

## 7.5.1.2 Control of production process changes

MWI 8040.2

60 Are persons authorized to approve changes to production processes identified (1) ?

61 Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements ?

62 Are changes affecting processes, production equipment, tools and programs documented ?

63 Are procedures available to control their implementation ?

MWI 8040.2

64 Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality ?

## 7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs

65 Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures ?

no sample noted

66 Does validation prior to production use include verification of the first article produced to the design data/specification ?

no sample noted

67 Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage ?

no sample noted

## 7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities

68 When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work ?

## Guidance Notes

- 1) Clearly defined list or procedures

## Objective evidence assessed / Observations / Comments / N/A explanation

change request - SSCN 3578 4/00

SSCN 8692 - verified authorized individuals

SSCN 003578 on MPLM (ISS-MPLM-PLAN-017

ISS-MPLM-PLAN-017 Rev C 10/03 Level 3 CCM in place (membership-CCB)

CBDI - MP3-00-0065

ECR - FD24-0032

Bldg 4619 - Air Quality Testing - record results noted on Tags

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action  
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management



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## ATTENDANCE ROSTER

CLIENT NASA - MSFC

ASSIGNMENT  
NUMBER

04/35812/TV02/AS-503

LOCATION Marshall Space Flight Ctr.

Alabama, 35812

AUDIT DATE June 22-25, 04

NAME PLEASE PRINT	TITLE	COMPANY	OPENING MEETING	CLOSING MEETING
Kerry Whicker	ASSISTANT MANAGER	NASA	✓	✓
MARY DEMURRAY	SR. QUALITY ENGINEER	Hernandez Engineering	✓	✓
Mike Sweigart	Proc. Analyst	NASA	✓	✓
T. Jerry Williams	Sup. Proc. Analyst	NASA	✓	✓
Jennifer Matthews	Contracting Officer	NASA	✓	✓
Karen Istikhar	EQ ISO Representative	NASA	✓	✓
PAT SCHAULTZ	HUMAN RESOURCES	NASA-MSE	✓	
JOHN PEA	ORG REP	NASA-MPO2	✓	✓
Bessie Lee	CM MPLM FD24	COLSA	✓	
Kathy Moorhead	DM NODES 2/3	COLSA-ED43	✓	✓
Lisa Cooper	NODES 2/3 CM	COLSA-ED43	✓	✓
MARTHA LOFTON	SP/FD/mp CM	NASA	✓	
Jim J. Lindsay	ED20	NASA	✓	
Caroline Wang	CD30/C&ER <sup>ISO</sup> Lead	NASA	✓	✓
Frank Knight	XPO1/SME	QTEC INC	✓	✓
DAN ADAMS	Environmental Engineer	NASA	✓	
JEFF SAXON	ED20	NASA	✓	
Dena Tell	Mgmt. Analyst	NASA	✓	✓
Billie Swinford	EO Mgr.	NASA	✓	✓
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NAME PLEASE PRINT	TITLE	COMPANY	OPENING MEETING	CLOSING MEETING
Terry J. Hamm	SEMA Alt. Org. Rep.	NASA/MSFC	X	X
Roy. W. Malone Jr	SEMA Deputy Dir	NASA/MSFC	X	X
Douglas Blackwell	TDA Asst. Dir	NASA/MSFC	X	
JIM CARTER	Dir, CENTER OPERATIONS	"	X	X
Tom FLEMING	Assoc Dir - SCIENCE	NASA/MSFC/SDO	X	
Shara Huegele	Org Rep, RS	NASA/MSFC	X	X
James B. Thomason	HET PAC Engineer	HET	X	X
DEBORAH Wills	DIRECTIVES MANAGER	NASA/MSFC	X	
Abbie Johnson	Paralegal Spec.	NASA/MSFC	X	X
Lloyd LOVE	Electronics Engineer	NASA/MSFC	X	X
Steve Durham	Manager, IRCD	NASA/MSFC	X	X
DOM AMATORE	Mgr-Media + C&ER (acting)	NASA/MSFC	X	
Maria Hicks	Org. Rep - CDO3	NASA/MSFC	✓	✓
J. Michael Cole	MSG Project Manager	NASA/MSFC	X	
Thomas S. DOLLMAN	SD ISO/MMS REP	NASA/MSFC	X	✓
Van Blankenship	Test & Eval, Control Systems Lead	NASA/MSFC	X	
Tim Coral	FACILITIES	NASA/MSFC	X	
TERESA VANHOOSER	FLIGHT PROJECTS	NASA/MSFC	X	
Ed Rebbke	Engineer / ISO Rep	NASA/MSFC	X	X
Wanda K Wood	Aud. Manager	NASA/MSFC	X	

# NQA ISO AUDIT EXIT BRIEFING SIGN IN SHEET

DATE: 06/25/04

ORG AUDITED: MSFC

BLDG/RM 4203/1201

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